K132291

MAY 2 0 2014

510(k) Summary

Submitter:

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Prepared on: July 18, 2013

Device Name: NAMSA Chemical Process Indicator Strip for Steam

Classification: Class II Medical Device, FDA Product Code JOJ, General Hospital

Common Name: Indicator/Chemical Process Indicator

Trade Name: NAMSA REF TST4-S

Predicate Devices: SteriTec Cross-Checks Indicator, REF CI 107
K951113
SteriTec Products Mfg. Co., Inc.

Statement of Intended Use:

The NAMSA Chemical Process Indicator Strip for Steam, REF TST4-S is intended for use with individual materials (i.e. pouches, pack, tray) to demonstrate that the material has been exposed to a steam sterilization process to distinguish between processed and unprocessed goods.

The NAMSA Chemical Process Indicator Strip for Steam will transition from an initial yellow color to a dark brown/black signal color when exposed to high temperature steam at the following time and temperature intervals as a process indicator:

- 121°C for 30 minutes (gravity cycle)
- 134°C for 3 minutes (pre-vacuum)

Description of Device: The NAMSA Chemical Process Indicator Strip for Steam utilizes NAMSA indicating ink SSI-10-YBI that when exposed to high temperature steam turns from an initial yellow color to a permanent dark brown/black signal color.

The intended use for the NAMSA Chemical Process Indicator Strip for Steam processes is a Process Indicator intended for use by health care facilities to distinguish between processed and unprocessed goods.

The NAMSA Chemical Process Indicator Strip for Steam will transition from an initial yellow color to a permanent dark brown/black signal color when exposed to high temperature steam at the following time and temperature intervals:

- 121°C for 30 minutes (gravity cycle)
- 134°C for 3 minutes (pre-vacuum)

The Indicating Ink was developed and validated for compliance with ANSI/AAMI/ISO 11140-1:2005 guideline. As such, the critical parameters are time, temperature and presence of saturated steam.

Table 1: Test and Performance Requirements for Class 1 Process Indicators for STEAM

Test Condition	Test Time	Test Temperature	No change or a change this is markedly different from the visible change as specified by the manufacturer	Visible change as specified by the manufacturer
Saturated Steam	3.0 min ± 5 sec	121°C (+3/0°C)	Acceptable result	Unacceptable result
Saturated Steam	10.0 min 0/-5 sec	121°C (+3/0°C)	Unacceptable result	Acceptable result
Saturated Steam	20sec	134°C (+3/0°C)	Acceptable result	Unacceptable result
Saturated Steam	0.5 min ± 5 sec	134°C (+3/0°C)	Acceptable result	Unacceptable result
Saturated Steam	2 min +5/0 sec	134°C (+3/0°C)	Unacceptable result	Acceptable result
Dry Heat	30 min ± 1 min	140°C (+2/0°C)	Acceptable result	Unacceptable result

Device compliance to ANSI/AAMI/ISO 11140-1:2005 & ANSI/AAMI ST-60:1996 is dependent upon substrate, thickness of ink application and presence of an over-laminate, reference material specification for NAMSA Chemical Process Indicator Strip for Steam.

Operational Principles:

The NAMSA Chemical Process Indicator Strip for Steam is intended for use with individual units, (e.g. packs, containers) to demonstrate that the goods have been exposed to a steam sterilization process and to distinguish between processed and unprocessed goods.

The NAMSA Chemical Process Indicator Strip for Steam will transition from an initial yellow color to a dark brown/black signal color when exposed to high temperature steam at various time and temperature intervals.

Statement of Similarity to Legally Marketed Predicate Device:

The NAMSA Chemical Process Indicator Strip for Steam has the following similarities to those legally marketed under 510(k) number K951113:

- Same intended use
- Same technological characteristics through device design, indicator agent, sterilization method and end point specifications and incorporation of similar materials
- Have similar shelf lives, and
- The same materials for packaging

A comparison of the characteristics of both the new device and predicate device and data resulting in equivalent performance has been generated.

Comparison of the New Device to the Predicate Device

Element	New Device	Predicate Device
	NAMSA Chemical Process Indicator Strip for Steam	**Cross-Checks Indicator**
Intended Use	Process Indicator	Process Indicator
Device Design and Components	Paper strip, 0.75" W x 4.5"L, 10 mil white tag stock Chemical indicator on BOPP film, Yellow to Dark, Indicator tamped onto paper strip Over laminate of PET	Paper strip, 0.5625" W x 7.66" L, 80 pound cover Chemical indicator, White to Dark, Indicator printed directly on paper strip Over laminate of PET
Indicator Agent	Indicating Ink NAMSA formulation SSI-10-YBI, Bismuth based agent to yield color transition	Indicating Ink Steritec formulation, Lead based agent to yield color change
Sterilization Method and Cycles	Steam 121°C 30 minutes (gravity cycle) Steam 134°C for 3 minutes (pre-vacuum cycle)	Steam 132°C - 135°C 3 Minutes standard hospital steam sterilizer
Endpoint Specifications	During steam sterilization, indicator goes from an initial yellow color to a dark brown/black signal color.	During steam sterilization, indicator goes from an initial white color to a dark brown/black signal color.
Shelf Life	17 Months	36 Months

The following tests were performed in accordance with ANSI/AAMI/ISO 11140-1:2005 for steam to verify the performance of NAMSA Chemical Process Indicator Strip for Steam was substantially equivalent to the predicate device.

- Steam Prevac at 121°C for 3 minutes
- Steam Prevac and Gravity at 121°C for 10 minutes
- Steam Prevac at 134°C for 20 seconds
- Steam Prevac at 134°C for 30 seconds
- Steam Prevac at 134°C for 2 minutes
- Dry heat at 140°C for 30 minutes

In summary, the data generated demonstrates NAMSA Chemical Process Indicator Strip for Steam is substantially equivalent to the predicate device.

Description of Testing:

Per the FDA recognized guidance document, testing was performed for steam sterilization processes using multiple lots of NAMSA Chemical Process Indicator Strip for Steam.

- Exposure at Various Times & Temperatures following ANSI/AAMI/ISO 11140-1:2005 for Steam
- Transference Testing per ANSI/AAMI/ISO 11140-1:2005
- Biocompatibility
- Shelf Life

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2014

North American Science Association Incorporated
Ms. Julie Wheeler
General Manager
6750 Wales Road
Northwood, OH 43619

Re: K132291
Trade/Device Name: NAMSA Chemical Process Indicator Strip for Steam
Regulation Number: 21 CFR 880.2800
Regulation Name: Indicator, Physical/Chemical Sterilization Process
Regulatory Class: Class II
Product Code: JOJ
Dated: April 17, 2014
Received: April 21, 2014

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K132291

Device Name: NAMSA Chemical Process Indicator Strip for Steam

Indications for Use: The NAMSA Chemical Process Indicator Strip for Steam, REF TST4-S is intended for use with individual materials (i.e. pouches, pack, tray) to demonstrate that the material has been exposed to a steam sterilization process to distinguish between processed and unprocessed goods.

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SINGLE USE ONLY

Prescription Use _____ (Part 21 CFR 801 SubpartD)

AND/OR

Over-The-Counter Use __X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000558 64, cn=Elizabeth F. Claverie -S
Date: 2014.05.19 16:36:26 -04'00'